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APR - 6 2012

510(k) SUMMARY

Date Prepared	January 11, 2012
Submitter's Name and Address:	DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
Contact Person	Susan Kagan Project Manager, Regulatory Affairs Telephone: 508-880-8097 Facsimile: 508-977-6911 e-mail: skagan@its.jnj.com
Name of Medical Device	Classification Name: Electrosurgical cutting and coagulation device and accessories: 21 CFR 878.4400 Common/Usual Name: Electrosurgical cutting and coagulation device and accessories: Arthroscope Proprietary Name: Side Effect with Hand controls Hook Electrode with Hand controls 2.3 Wedge Electrode with Hand controls S90 with Hand controls P50 with Hand controls FDA Classification: II FDA product code: GEI
Predicate Device(s)	The proposed **P50 Electrode with Handcontrols** is substantially equivalent to: ▪ K002422: VAPR 90° Suction Electrode (August 31, 2000) ▪ K082643: VAPR Electrodes with Handpieces (December 19, 2008) ▪ K100638: VAPR VUE including CP90 Handcontrol (June 18, 2010)

The proposed **S90 Electrode with Handcontrols** is substantially equivalent to:

- K041135: VAPR LPS Electrode (May 10, 2004)
- K082643: VAPR Electrodes with Handpieces (December 19, 2008)
- K100638: VAPR VUE including CP90 Handcontrol (June 18, 2010)

The proposed **Side Effect, Hook** and **Wedge Electrode with Handcontrols** are substantially equivalent to:

- K963783 Mitek Electrosurgical System (December 25, 1996)
- K082643 VAPR Electrode with Integrated Electrode (December 19, 2008)
- K100638 VAPR VUE including CP90 with handcontrols (June 18, 2010)

Device Description

The VAPR Electrodes with Handcontrol are similar in technological characteristics, geometry and materials, as their predicated except they will now be available with integrated handcontrol capabilities via three buttons mounted on the existing one-piece handles.

These buttons control ablation, coagulation and the generator mode functions. The plug of the electrode is designed to fit the VAPR VUE generator (K100638: June 18, 2010) socket only and houses the components for ID recognition. They are intended to be run only off the VAPR VUE platform at pre-determined default settings specific for the device. If required, the settings for the device can be modified within safe pre-determined limits by accessing the generator or footswitch control in addition to the buttons on the handpiece.

There are no changes being made to the fundamental technology of the electrode with the exception of the addition of handcontrol functionality.

Indications for Use

The DePuy Mitek VAPR Electrodes for use with the VAPR System are intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, and wrist.

Comparison to Predicate Device

This submission is intended to demonstrate that the VAPR Electrodes with handcontrols are substantially equivalent to their legally marketed devices.
The Electrodes have been carefully compared to legally marketed devices with respect to intended use, essential components and material, performance specifications and technology characteristics.

All of the electrodes which are the subject of this submission have the same Indications for Use and technology characteristics. The change to these electrodes is the addition of handcontrol capability which uses the same fundamental technology as the CP90 Electrode and VAPR footswitch.

In addition, safety and performance testing have been done to validate the performance and safety of the device. It has been demonstrated that the addition of handcontrol capability to their predicate electrodes will not affect safety and effectiveness of the subject devices.

Safety and Performance

Verification of the VAPR Electrodes with handcontrols includes performance testing to show that the device meets its product specifications. Results of performance testing are summarized in Table 1.

Table 1.

Test	Results
One Piece Cantilever Handle Separation Test	Pass
One Piece Handle Retention Test	Pass
Fluid Ingress Test for Finger switches	Pass
System Compatibility Test	Pass
Capacitance Test	Pass

Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The VAPR Electrodes with handcontrols do not differ from the predicate device in fundamental scientific technology or intended use.

Conclusion

Results of performance and safety testing have demonstrated that the modified device is suitable for its intended use.

Based on the indications for use, fundamental scientific technology, and comparison to the predicate devices, the VAPR Electrodes with handcontrols which are the subject of this submission are shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Ms. Susan Kagan
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APR - 6 2012

Re: K120095
Trade Name: VAPR electrodes with Hand Controls
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 22, 2012
Received: March 23, 2012

Dear Ms. Kagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120095

Device Name: **VAPR Electrodes with Handcontrols**

Indications for Use:

The DePuy Mitek VAPR Electrodes for use with the VAPR System are intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, and wrist.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120095